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Title

A secondary analysis of a randomised controlled trial to investigate the effect of Tai Chi on the instrumented Timed Up and Go test in people with mild to moderate dementia

Running Head

Tai Chi on iTUG in persons with dementia

Authors

Jonathan Williams¹, PhD

Samuel Nyman², PhD

1. Department of Rehabilitation and Sports Sciences, Faculty of Health and Social Sciences, Bournemouth University, Poole, UK. Orchid-iD 0000-0001-8331-3181
2. Department of Psychology and Ageing & Dementia Research Centre, Faculty of Science and Technology, Bournemouth University, Poole, UK. Orchid-iD 0000-0003-1963-0814

Corresponding Author

Jonathan Williams, Royal London House, Bournemouth University, Christchurch Road, Bournemouth, Dorset, UK. BH1 3LT.

jwilliams@bournemouth.ac.uk

01202 962748

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NCT02864056

29 A secondary analysis of a randomised controlled trial to investigate the effect of Tai Chi on
30 the instrumented Timed Up and Go test in people with mild to moderate dementia

31

32 Abstract

33 Background

34 Previous research has identified that Tai Chi is effective for reducing risk of falls and
35 improving Timed-Up and Go scores. However, our previous research identified no-
36 significant difference in time to complete the Timed-Up and Go test following a Tai Chi
37 intervention in people with dementia.

38 Aim

39 To conduct a secondary analysis to extend our understanding of the effect of Tai Chi on the
40 instrumented Timed-Up and Go test.

41 Methods

42 Secondary analysis of a randomised controlled trial set in the community. People with
43 dementia, recruited from NHS databases, memory clinics, local charities and self-referral
44 across the south of England, received either 20 weeks of Tai Chi plus normal care or normal
45 care. Outcomes were assessed using the instrumented timed-up and go test, completed at
46 baseline and after 6 months.

47 Results

48 From 83 people with dementia volunteering for the study 67 complete datasets were available
49 for analysis. Within group pairwise comparison across time revealed no-significant gains for
50 any of the instrumented Timed-Up and Go variables, and no-significant difference for
51 between group pairwise comparisons.

52 Discussion

53 This suggests Tai Chi had no effect on [the instrumented Timed-Up and Go](#) in people with
54 dementia. This lack of effect may be due to the lack of specificity of the training stimulus to
55 the outcome measure.

56 Conclusion

57 Tai Chi had no effect on any [instrumented Timed-Up and Go](#) variables, suggesting Tai Chi
58 may not be best placed to enhance the sub-elements of the [instrumented Timed-Up and Go](#) to
59 reduce fall risk among community-dwelling people with dementia.

60

61

62 Key words

63 Balance, Gait, Turning, Sit to stand, Intervention, Clinical trial.

64

65 Abbreviations

66 PWD, people with dementia

67 iTUG, Instrumented Timed Up and Go

68

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70

71 Falls among older people are globally recognised as a public health issue [1]. Falls in later
72 life can result in injuries that require hospitalisation and reduce independence [2], and
73 subsequently reduce quality of life and increase costs on health and social services [3]. A risk
74 factor for falling is cognitive impairment, and in particular dementia; a degenerative
75 neurological disease characterised by a chronic, global, and non-reversible loss of cognitive
76 functioning [4]. People with dementia (PWD) are more than twice as likely to fall and twice
77 as likely to experience injurious falls compared to their cognitively intact peers [5,6].

78

79 There is robust evidence for interventions, and in particular exercise-based interventions, to
80 prevent falls and fall-related injuries among community-dwelling people without cognitive
81 impairment [7-9]. This includes Tai Chi exercise interventions: A meta-analysis found Tai
82 Chi to reduce falls among the general healthy older adult population and those at risk of falls
83 by on average 31% (incident rate ratio [IRR] = 0.69, 95% confidence interval [CI] = 0.60,
84 0.80, 15 trials) and the number of people falling at least once by 20% (IRR = 0.80, 95% CI =
85 0.72, 0.88, 16 trials) [12]. Furthermore, a meta-regression of 108 exercise trials with
86 community-dwelling older people found that Tai Chi was one of three exercise programmes
87 that are effective in reducing falls [13]. However, to date, only three exercise trials have been
88 conducted with community dwelling PWD [10,11,14]. We recently conducted a randomised
89 trial to test the effect of Tai Chi exercise on improving postural balance among PWD [15]. It
90 was also a feasibility study for a subsequent definitive trial to test the effect of Tai Chi on
91 preventing falls among PWD. Tai Chi is an ancient form of Chinese mind-body exercise,
92 where participants carry out smooth and continuous body movements along with deep
93 breathing and mental concentration [16]; equivalent to moderate-intensity exercise and quiet
94 meditation [17]. This form of exercise is particularly suited for PWD with its use of slow and
95 repetitive movements [18].

96

97 The results of our recent trial suggested that PWD in the Tai Chi group, relative to a usual
98 care control group, at 6-month follow-up had significantly greater scores for quality of life,
99 and a strong trend for a reduction in falls [19]. However, these results were despite finding no
100 difference between the Tai Chi and control group on measures of balance including the timed
101 up and go test (primary outcome) [19]. The timed up and go test requires participants to
102 stand, walk 3 metres, turn, walk back, and return to a seated position [20]. Such a test is well
103 documented to predict faller from non-fallers [21-23] [as well as predict development of](#)
104 [future dementia in a sample of over 49000 \[24\]](#). Despite this predictive ability, the overall
105 measure of time to complete, masks the individual subcomponents that, if isolated, could be
106 analysed to identify early physical impairments [21]. Therefore, the instrumented timed up
107 and go test (iTUG) has been proposed [22] and has been found to be a reliable and valid
108 measure of physical performance [22-24]. Furthermore, the iTUG has demonstrated greater
109 discriminatory ability than total time to complete TUG in those with mild cognitive
110 impairment [21,26,27]. [Such approaches were also able to provide specific insights into](#)
111 [performance differences of those with a diagnosis of dementia compared to those without](#)
112 [\[28\]](#).

113 In light of the potential for the iTUG to reveal undetected physical improvements among
114 PWD from practising Tai Chi, we conducted an ad hoc secondary analysis of the trial data.
115 We hypothesised that PWD in the Tai Chi group would have superior scores on the iTUG at
116 follow-up relative to the control group, and that these scores would be correlated with the
117 observed trend for a reduction in falls in the Tai Chi group during the 6-month follow-up
118 period relative to the control group.

119

120 Methods

121 This study utilises data obtained as part of the TACIT trial (NTC02864056), a randomised
122 controlled trial to investigate the impact of Tai Chi on balance in PWD and their informal
123 carers. Ethical approval was granted by the West of Scotland Research Ethics Committee 4
124 (reference: 16/WS/0139 and the Health Research Authority (IRAS project ID: 209193). A
125 detailed breakdown of the TACIT protocol has been previously published [15].

126

127 Participants

128 PWD and their informal carers were recruited from NHS databases, local charities, memory
129 clinics and through self-referral from around the South of England. To meet inclusion, PWD
130 were aged 18 or over with a formal diagnosis of dementia (indicated by their NHS medical
131 records), living at home and were able and willing to complete weekly standing Tai Chi
132 without physical assistance. Exclusion criteria included being in receipt of palliative care,
133 living in a care home, severe dementia (defined as 9 or less on the Mini-Addenbrooke's
134 Cognitive Evaluation) [29], a Lewy body dementia or dementia with Parkinson's disease,
135 severe sensory impairment, currently under the care of or have been referred to a falls clinic,
136 or lacked mental capacity to provide informed consent. In addition, PWD were excluded if
137 they were currently completing or had recently completed Tai Chi or similar.

138

139 Randomisation

140 PWD were randomised using a centralised web-based randomisation system maintained by
141 the UKCRC-registered Peninsula Clinical Trials Unit to either receive usual care plus Tai Chi
142 or usual care (control group) in a 1:1 ratio. Minimisation was used within each site by
143 treatment condition and 12-month fall history at baseline. All individuals involved with data
144 collection were blinded to group allocation.

145

146 The sample size was based on that used for the Tacit trial [15]. The study was powered at
147 90% to achieve a difference of 4 seconds in total time to complete TUG, with a standard
148 deviation of 0.38, a correlation of 0.7 and a two sided 5% significance level. This yielded a
149 target recruitment of 120. While the recruited sample was below target at 83 PWD and carers,
150 smaller standard deviations than estimated were observed for the TUG and the estimated
151 smallest detectable change of a value of 4 was outside the 95% confidence interval (-2,17,
152 3.81) between the trial arms, suggesting that the testing on the TUG was adequately powered.

153

154 Intervention

155 Usual care could include medications and support services, social groups, peer support but
156 with an absence of exercise prescription. The intervention group continued usual care but
157 added Tai Chi comprising of 3 elements: (1) Tai Chi classes, (2) home based Tai Chi practice
158 completed with carer and (3) behaviour change techniques (including action panning, coping
159 planning, self-monitoring, feedback and social support) [15]. Classes were weekly and
160 comprised of 45 minutes instructor led Tai Chi followed by 45 minutes informal discussion
161 over 20 weeks. Classes were held in a variety of suitable venues such as church halls. Home
162 based Tai Chi was based on repetition of the taught material with an aim to accrue 50 hours
163 practice. Tai Chi instructors were all experienced Tai Chi trainers and had qualifications to
164 senior instructor level.

165

166 Instrumentation

167 A miniature balance sensor device, housing an integration of triaxial accelerometer and
168 triaxial gyroscope (THETAmatrix, Portsmouth, UK) sampling at 30Hz was attached to the
169 low back, reinforced with elasticated strap. The device provides data pertaining to linear
170 accelerations and rotational velocities which was exported to MatLab where a bespoke

171 algorithm determines the features of importance from the TUG. Details regarding the
172 algorithm have been reported previously [30] and excellent reliability of the device has been
173 determined [31]. Outcomes (listed in table 2) relating to the sit to stand phase, the two
174 walking phases and two turning phases are retrieved through the bespoke algorithm
175 previously described [30].

176

177 All iTUG data were collected within the individual's home and the iTUG comprised of a
178 standard definition of stand from sitting, walk three-metres, turn, walk back and sit down.
179 One iTUG only was completed. No guidance was provided for direction of turn and the
180 distance was marked with tape on the floor. A pragmatic approach to chair selection was used
181 but every effort was made to complete the follow up using the same chair. All iTUG data was
182 collected without knowledge of group allocation. In addition to baseline iTUG performance,
183 iTUG was repeated after 6 months post-baseline. **In addition, to determine baseline function,**
184 **a Berg balance scale was completed by the same individual [32].**

185

186 Statistics

187 All iTUG variables were not normally distributed therefore non-parametric statistics were
188 used to explore differences. Between group pairwise comparisons were made using Mann-
189 Whitney-U tests at baseline and at follow-up. In addition pairwise comparisons were made
190 using Wilcoxon tests, within group, across the two time points (baseline and follow-up) for
191 both the control and intervention group. A Bonferroni correction was applied to minimise the
192 chance of type 2 error and thus an alpha of 0.004 was used to determine statistical
193 significance.

194

195 Results

196 Over the period of between 06/04/2017 to 17/07/2018, 359 individuals were approached with
197 85 agreeing to participate. Two individuals were erroneously diagnosed with dementia and
198 were removed, from which data for 67 PWD was available at baseline and 6 month follow
199 up. 13 individuals were lost to follow up and 3 individuals were removed due to data
200 collection error (1 from intervention group and 2 from usual care group). This resulted in 33
201 for the intervention group and 34 for the control group, see figure 1 or [19]. No serious
202 adverse events relating to participation were noted. There were no differences at baseline
203 between the groups, including cognitive function (Table 1).

204

205 Baseline scores and score at six month follow up for iTUG for the 2 groups can be found in
206 table 2. Between group pairwise comparisons demonstrated no significant differences
207 between the intervention group and control group at both baseline and at follow-up for any
208 iTUG variable. Within group pairwise comparisons demonstrated that in the intervention
209 group there was a significant reduction in turning velocity for the second turn ($p = 0.002$) at
210 follow-up, compared to baseline. No other significant differences were evident at follow-up
211 in the intervention group. In the control group there was a significant reduction in the turning
212 velocity of the first turn ($p = 0.003$). No other significant difference were determined in the
213 control group at follow-up.

214

215 Discussion

216 The aim of this study was to explore the effects of Tai Chi on iTUG in people with dementia.
217 Previously it was identified that there was no significant difference in total time to complete
218 the TUG [19] and this study adds to the understanding by demonstrating that this lack of
219 effect is evident across all sub phases of the iTUG. This provides new comprehension, as
220 each sub phase of the iTUG constitutes suitable or large differences in their underlying

221 physiological constructs (i.e. quadriceps power for sit to stand, coordination for turning etc.),
222 however despite this, none appeared to be modified by Tai Chi, suggesting a universal lack of
223 treatment effect on iTUG.

224 These results are in conflict with other studies that have demonstrated significant
225 enhancement in the total time to complete TUG following Tai Chi in older adults and
226 individuals with Parkinsons Disease [33,34].

227 The lack of effect may be explained by insufficient treatment dose. If the Tai Chi intervention
228 lacked the magnitude and intensity to yield any physiological change then this could possibly
229 explain the lack of change demonstrated in the iTUG. Fidelity of the intervention has been
230 reported previously [19], and all participants were able to understand and follow the Tai Chi
231 instructions. The mean supervised Tai Chi practice time was 8.4 hours, which is less than half
232 of that offered by Zou et al [35], who demonstrated significant reductions in total time to
233 complete iTUG. However the magnitude of change was less than 1 second on a baseline of
234 10.1seconds, suggesting a minimal change on the background of minimal impairment, both
235 of which are different to the current study. However, Hosseini et al [36], delivered a similar
236 amount of supervised Tai Chi to the current study which resulted in a 6.7 second
237 improvement in total time to complete iTUG using a sample with a baseline score similar to
238 the current study. It is not clear if the intensity was different and thus the Tai Chi more
239 effective or whether the presence of cognitive impairment in our sample of PWD can explain
240 the difference in the studies. The current study also included an additional mean of 16.5 hours
241 of Tai Chi home practice resulting in 23.6 hours of Tai Chi practice. The study set out to
242 achieve 50 hours therefore adherence remains a challenge. Despite this it is acknowledged
243 that the concept of ‘dose’ is poorly understood and there is a lack of understanding of the
244 specific dose of Tai Chi necessary within this population to yield a change. Further research
245 is required to establish a dose response relationship for Tai Chi in people with dementia.

246 Another possible explanation for the lack effect may lie with the lack of improvement in Tai
247 Chi. It is highly probable that through repetitive practice, PWD will develop an enhanced
248 capacity for actually completing the Tai Chi movements. This enhanced capacity through a
249 combination of learning and physiological adaptation i.e. they become better at the routines,
250 and the muscles and movement patterns become stronger and easier. This would then
251 ultimately carry over into enhanced function witnessed in the sub-phases of the iTUG.
252 However if, despite the repetitive practice, the PWD demonstrated no improvement in Tai
253 Chi this would suggest that this process of adaptation had not occurred thus offering an
254 explanation for lack of effect. No measures of ability to complete Tai Chi were taken
255 therefore this remain speculative.

256 It may be possible that the iTUG was not the optimal measure to detect change following Tai
257 Chi. It is possible the iTUG lacked the sensitivity and specificity to detect change following
258 the intervention. Minimal detectable change values for the total time to complete iTUG have
259 been established but this is not the case for the sub-phases of iTUG. Moreover changes in
260 balance and physical functioning may have been enhanced through Tai Chi but were not
261 captured through the measurement of iTUG. The iTUG is comprised of sub-phases each of
262 which has a different underlying construct. For example to demonstrate high vertical
263 acceleration during sit to stand requires lower limb power and to turn rapidly requires, among
264 other things, rapid asymmetrical coordination. It is possible that, through Tai Chi, with its
265 mindful, slow, moving meditation this training stimulus may not be best placed to enhance
266 higher order temporal kinematics such as velocity and acceleration. This so-called specificity
267 principle of training is well understood and may offer an explanation as to why velocities and
268 acceleration were unchanged [37]. Indeed, in studies investigating the effects of exercise
269 prescribed to closely match the demands of the task, significant change has been
270 demonstrated, in this example for turning duration [38].

271 It is further possible that the lack of effect witnessed is a result of a lack of statistical power
272 due to the smaller sample size recruited than planned. This resulted in a reduction of
273 statistical power from the planned 90% to 69% [19]. This poses the question, if the sample
274 size was greater would the study have been sufficiently powered to achieve statistical
275 significance? It has often been recommended to calculate post hoc power or observed power,
276 however this does not provide insights beyond those observed with statistical tests [39]
277 mainly because of the relationship between the p-value and observed power [40]. This
278 approach is therefore not recommended [40]. In clinical studies such as this more important is
279 to observe the magnitude of actual changes (mean difference, table 2). These values are small
280 with some positive, some negative and all confidence intervals crossing zero suggesting no
281 effect cannot be ruled out [41] and the clinical benefits of the intervention, on the iTUG, were
282 minimal, if any. The numbers provided could be used to determine effect sizes for future
283 studies.

284 This is the first study to explore the effects of Tai Chi on iTUG in PWD and thus represents a
285 novel contribution to the literature. It seems possible that generating the parameterisation of
286 the Timed Up and Go test is quick, simple and possible within an individual home
287 environment.

288 Study Limitations

289 A number of limitations should be acknowledged. Firstly a pragmatic approach to chair
290 selection was adopted as all data were collected in the individual's home. Every attempt was
291 made to ensure the same chair was used for follow up but it is possible that chairs differed
292 between individuals. This is true also for the environment in which the iTUG was completed.
293 Again intra-individual variability was minimised but between individual differences were

294 possible. Secondly it is acknowledged that there was not 100% compliance with Tai Chi
295 especially the home practice element.

296 Conclusions

297 This study identified that there were no differences in performance between the control group
298 and the Tai Chi group in their ability to complete the iTUG, regardless of sub-phase. This
299 suggests that such an intervention had no impact on physical performance of iTUG, therefore
300 if improvements to iTUG are a clinical aim then modifications to the treatment offered in this
301 study required.

302

303

304 **Declarations**

305 Funding

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309 expressed are those of the authors and not necessarily those of the NHS, the NIHR or the
310 Department of Health and Social Care.

311 Conflict of Interest

312 Dr Jonathan Williams has consulted with THETAmetrix the company from which the sensor was
313 purchased.

314 Availability of data and material

315 Data can be made available on reasonable request.

316 Code availability

317 NA

318 Ethics approval

319 Ethical approval was granted by the West of Scotland Research Ethics Committee 4
320 (reference: 16/WS/0139 and the Health Research Authority (IRAS project ID: 209193)).

321

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- 436

437

438 Table 1. Baseline characteristics between groups.

	Intervention Group	Control Group
Female n (%)	14 (42%)	13 (38%)
Mean age (sd)	78.6 (8.4)	78.3 (8.0)
M-ACE (sd)	16.5 (5.2)	15.6 (4.5)
Berg Balance Scale	44.6 (5.9)	44.3 (7.5)

439 M-ACE; Mini-Addenbrooke's Cognitive Evaluation.

440

441 Table 2. Instrumented Timed-Up and Go variables at baseline and 6 months for the
 442 intervention and control group.

	Intervention Group		Control Group		Mean difference 95% CI
	Baseline Median (IQR)	Follow-up Median (IQR)	Baseline Median (IQR)	Follow-up Median (IQR)	
Standing Acc (ms⁻²)	-1.56 (0.91)	-1.38 (0.58)	-1.54 (0.58)	-1.50 (0.73)	0.01 (-0.20, 0.22)
S2S duration (s)	2.16 (0.63)	2.10 (1.17)	2.03 (1.04)	1.94 (0.67)	-0.33 (-1.08, 0.41)
Walk 1 duration (s)	4.44 (2.25)	4.32 (3.08)	4.05 (2.25)	4.10 (2.10)	0.77 (-0.40, 1.94)
Walk 2 duration (s)	3.81 (2.03)	3.49 (2.63)	3.51 (2.74)	3.71 (3.11)	0.28 (-0.77, 1.32)
Turn 1 duration (s)	2.54 (0.79)	2.95 (0.73)	2.70 (0.69)	3.08 (0.67)	0.22 (-0.55, 0.98)
Turn 1 Vel (°/s)	1.71 (0.62)	1.79 (0.40)	1.93 (0.81)	1.70 (0.57)*	-0.04 (-0.21, 0.12)
Turn 2 Vel (°/s)	1.80 (0.90)	1.67 (0.82)*	1.95 (0.91)	1.61 (1.23)	-0.30 (-0.49, -0.10)
AC Step walk 1	0.63 (0.52)	0.59 (0.41)	0.63 (0.40)	0.59 (0.37)	-0.38 (-0.86, 0.11)
AC Stride walk 1	0.74 (0.54)	0.62 (0.54)	0.62 (0.43)	0.53 (0.42)	-0.42 (-0.88, 0.05)
Step/Stride Ratio 1	1.02 (0.17)	0.96 (0.34)	1.05 (0.50)	0.99 (0.40)	0.09 (-0.22, 0.40)
AC Step walk 2	0.79 (0.42)	0.54 (0.47)	0.52 (0.46)	0.65 (0.49)	-0.18 (-0.37, 0.01)
AC Stride walk 2	0.79 (0.18)	0.69 (0.34)	0.68 (0.43)	0.66 (0.34)	-0.20 (-0.40, -0.00)
Step/Stride Ratio 2	0.98 (0.30)	0.81 (0.37)	0.87 (0.42)	0.90 (0.49)	-0.15 (-0.32, 0.03)

443 * p < 0.004. IQR; interquartile range, Acc; Acceleration, S2S; sit to stand, Vel; Velocity, AC;
 444 Autocorrelation.

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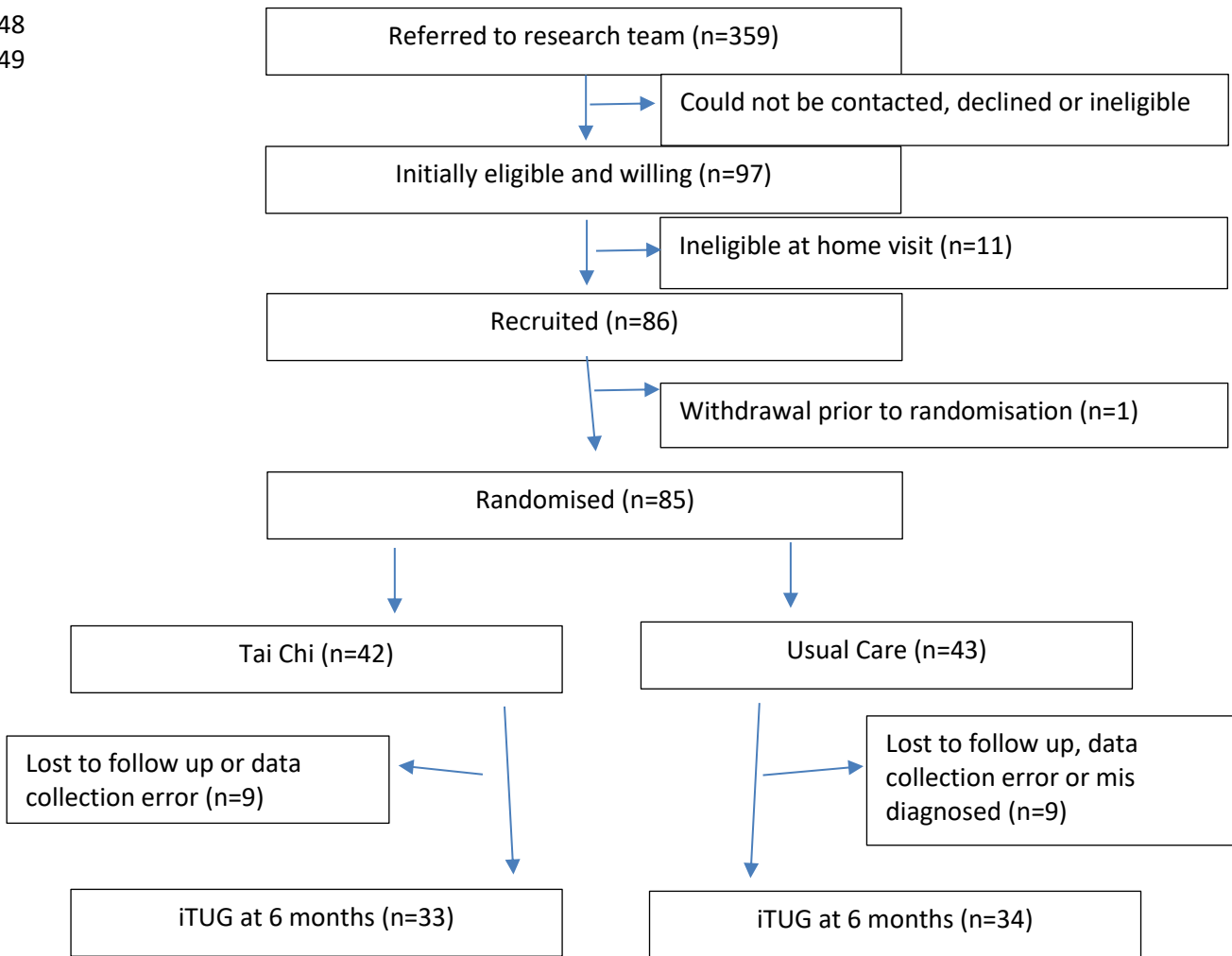


Figure 1. Flow diagram of study participation